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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,594	02/12/2001	John R. Bianchi	RTI- 112R	9490

7590 03/24/2005

DONALD J. POCHAPIEN
McANDREWS, HELD & MALLOY, LTD.
CITICORP CENTER, 34TH FLOOR
500 WEST MADISON STREET
CHICAGO, IL 60661

EXAMINER

PREBILIC, PAUL B

ART UNIT PAPER NUMBER

3738

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

8W

Office Action Summary	Application No.		Applicant(s)	
	09/782,594		BIANCHI ET AL.	
	Examiner		Art Unit	
	Paul B. Prebilic		3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/1/04</u> . | 6) <input type="checkbox"/> Other: _____ |

Drawings

A proposed drawing corrections filed January 24, 2005 have been approved for entry.

Upon review of present claims over the subject matter of the various parent applications and related applications, it was determined that claims 26-33 have an effective filing date of February 12, 2001. In particular, claims 26-31 and 33-34 have this date because of the "one or more . . pins", "two or more" or "three" connected bone portions in combination with bone pins; there are only 2 bone portions and 4 pins set forth as the sole example in the parent application (see Figure 7 and page 17 of 08/920,630). Furthermore, claims 30 and 32 have this date because of the "cancellous" bone portions where the implant constitutes two or more portions that have been connected together by press fitting.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 26-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 79 of copending Application No. 09/941,154. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claim 79 is read on by what is set forth in the claims of this application such claim 79 would be anticipated thereby. For this reason, the claims are considered obvious in view of claim 79; see *In re Goodman, supra*.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

Claim 29 is objected to because of the following informalities:

On line 2 of claim 29, the use of "comprising" is confusing because the bone graft has several other elements already set forth in the base claim. For this reason, the Examiner suggests replacing "comprising" with ---where there are--- in order to overcome this objection. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. On line 4 of claim 27, "said composite bone graft" lacks antecedent basis, and thus, the claim scope is considered to be indefinite.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26-31 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al (US 6,200,347). Anderson anticipates the claim language where the bone portions as claimed are the bone grafts (16 and 17 of Figure 7 or elements 2 and 4 of Figure 1) and the pins of Anderson are threaded and do not contain adhesive (see column 5, lines 29-33); see also column 19, line 62 to column 20, line 36 and column 5, lines 1-8. The interference fit of Anderson with a smaller hole than the pin is considered to be the same as a press fit; see column 5, lines 29-33.

Claims 26-28, 30, 31, 33, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellis (US 5,147,367). Ellis anticipates the claim language where the bone pieces or bone portions of the same patient are grafted back onto the bones they were separated from to form a graft; see the figures, the abstract and column 5, lines 12-56. "Graft" is denoted as "anything inserted into something else so as to become an integral part of the latter"; Stedman's Medical Dictionary, 23rd Edition, p. 599. For this reason

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the separated bone piece(s) are grafts when this term is given its broadest reasonable interpretation.

With regard to claim 27, the breaks or separations are in cortical bone because cortical bone is on the outside of bone and it is visible in the drawings.

With regard to claim 28, the pins of Ellis are cortical bone pins because they are for cortical bone the same way a "bone screw" is for bone but can be made of a metal.

Claims 26, 27, 31, and 33-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Ochoa (US 5,716,358). Ochoa meets the claim language where the bone pieces or bone portions of the same patient are grafted back onto the bones they were separated from to form a graft; see the Figures 4 and 5 as well as column 6, line 57 to column 8, line 47. "Graft" is denoted as "anything inserted into something else so as to become an integral part of the latter"; Stedman's Medical Dictionary, 23rd Edition, p. 599.

Claims 26-31 and 33-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Yaccarino, III (US 6,025,538). Yaccarino anticipates the claim language where two or more bone portions are joined with two bone pins; see Figures 8 to 15 and column 5, line 55 to column 7, line 14.

With regard to claim 29, Applicants are directed to column 9, lines 55-67.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yaccarino, III (US 6,025,538) alone. Yaccarino meets the claim language as set forth in the previous rejection, but fails to teach a cancellous bone portion press-fitted in the hole as claimed. However, Yaccarino prefers cortical bone for his press-fitted pins and states that allograft bone contains both cortical and cancellous bone; see column 1, lines 31-45. Yaccarino adds that allograft is used to make bone pins. Therefore, it is the Examiner's position that it would have been considered prima facie obvious to make the pins of Yaccarino with some cancellous bone in order to better encourage bone ingrowth throughout the implant.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but were not considered persuasive.

In response to the argument that all the claims have an effective filing date of August 23, 1997, the Examiner does not agree and has altered the explanation above to point out where the support is lacking. In particular, claims 26-31 and 33-34 have the effective filing date of February 12, 2001 because the subject matter of "one or more . . pins", "two or more" or "three" connected bone portions in combination with bone pins was not disclosed in 08/920,630; there are only 2 bone portions and 4 pins set forth as the sole example (see Figure 7 and page 17 of 08/920,630). Furthermore, claims 30 and 32 have this date because of the "cancellous" bone portions where the implant

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constitutes two or more portions that have been connected together by press fitting was not disclosed in the parent application.

The remaining argument of the November 22, 2004 response were rendered moot in view of the new grounds of rejection set forth.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.


Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Paul B. Prebilic
Primary Examiner